IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

(1) SUSAN SCHROCK and (2) STEVE SCHROCK,)	
Plaintiff,)	
VS.)	CASE NO. 5:08-cv-453-M
(1) PLIVA USA, INC. (2) QUALITEST PHARMACEUTICALS) S, INC.)	
Defendants.)	

AMENDED AGREED PROTECTIVE ORDER

WHEREAS, Rule 26(c) of the Federal Rules of Civil Procedure provides for the issuance of protective orders limiting the disclosure of discovered information in appropriate circumstances. [DKT 134]

Whereas, Qualitest Pharmaceuticals, Inc. ("Qualitest") was recently added as a defendant to this case on April 14, 2010, and seeks to limit and protect the disclosure of certain designated information consistent with the Agreed Protective Order previously entered by this Court.

Therefore, the court finds good cause for the entry of this Amended Agreed Protective Order under Federal Rule of Civil Procedure 26(c) and hereby ORDERS that all documents and other information produced in this case by the parties shall be produced subject to the following:

1. SCOPE

A. At any time prior to the production of any documents or information by the producing party, it may designate such information or documents as confidential and subject to this Amended Agreed Protective Order. The producing party shall further designate material as confidential and subject to this Amended Agreed Protective Order by placing the following or substantially similar marking on each copy of each document copied for, by, or on behalf of plaintiffs or co-defendants in this action in a manner which will not interfere with its legibility:

"CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." Documents or information designated shall be referred to herein as "Confidential Discovery Material."

B. This Amended Agreed Protective Order shall apply to and govern all documents and information designated by the producing party as confidential whether or not such documents or information are informally produced or produced in response to formal discovery requests. The producing party may designate those specific answers to interrogatories, responses to other discovery requests, and excerpts of deposition testimony as confidential and protected by this Amended Agreed Protective Order. With respect to deposition testimony, the designation of confidentiality may be made on the record at the time of the deposition, at which time the testimony and transcript thereof shall be subject to

the full protection of this Amended Agreed Protective Order. Within thirty (30) days after the completion of the deposition, counsel for the party asserting confidentiality shall clarify all portions to which it claims confidentiality. In the case of testimony not so designated during the course of a deposition, counsel for the producing party may, at any time within thirty (30) days of the completion of the deposition, notify the parties that the deposition testimony contains confidential material, in which case the testimony and transcript thereof shall be subject to the protection of this Amended Agreed Protective Order. During the thirty (30) day period, the testimony will be treated as though it had been designated as confidential pursuant to the terms of this Amended Agreed Protective Order. "Confidential Discovery Material" includes deposition testimony designated as confidential.

- C. Plaintiffs' Medical Records
- (1) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prescribes two methods by which a person's medical records may be collected by another party. 45 C.F.R. §164.512(e)(1)(i) & (ii). Both methods require the entry of protective order prior to the production of a person's medical records. See Id. and Fields v. West Virginia State Police, No. 2:09-cv-0754 (S.D. W. Va. Jan. 26, 2010), 2010 WL 286635 at *3.

- (2) All medical records of the Plaintiff(s) are to be deemed confidential unless otherwise ordered by the Court regardless of whether they are marked "CONFIDENTIAL".
- D. Any confidential Discovery Material that is filed with the Court, and any pleading, motion, or other paper filed with the court that reveals the content of any such Confidential Discovery Material, shall be filed under seal and shall bear the legend:

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION COVERED BY AN AMENDED AGREED PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT AGREED PROTECTIVE ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT.

This Amended Agreed Protective Order allows parties to file Confidential Discovery Materials under seal without a motion to file the documents under seal. Such Confidential Discovery Material and/or other papers shall be kept under seal until further order of the Court; however, Confidential Discovery Material and other papers filed under seal shall be available to the court and counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Amended Agreed Protective Order. The party wishing to use the Confidential Discovery Material also agrees to submit such information sealed for the court's in-camera inspection only.

- D. Use of Confidential Discovery Material subject to this Amended Agreed Protective Order at trial will be determined by subsequent agreement of the parties or order of this Court. However, the use of any confidential document at trial does not remove the protection afforded by this Amended Agreed Protective Order. Any confidential documents admitted into evidence will be returned to counsel at the conclusion of any trial and the confidential nature shall not be deemed waived by the use at trial.
- E. Confidential documents or information produced by Qualitest Pharmaceuticals, Inc., in prior litigation that are already in the possession of plaintiffs' counsel may be used pursuant to the terms of this Amended Agreed Protective Order. All documents or information so produced shall remain subject in all respects to all protections provided by this Amended Agreed Protective Order even though they have not been designated with the specific markings described in Paragraph 1.A. Documents or information stamped as or otherwise marked as "confidential" in prior litigation shall suffice. Their contents or existence shall not be disclosed by plaintiffs or co-defendant(s) except as provided in this Amended Agreed Protective Order. The foregoing provision does not apply to documents no longer considered confidential.

2. <u>TERMS OF PROHIBITION</u>

A. The documents and information provided by the producing party and designated as confidential shall be revealed only to, (1) counsel of record for the

parties in this action; (2) paralegals or secretarial employees under the direct supervision or employ of counsel of record in this action; (3) retained experts of the parties, provided, however, that no confidential information shall be disseminated to any expert who is employed or affiliated with a direct business competitor (i.e., in the business of pharmaceutical manufacturing or distribution) of any defendant or its affiliates; (4) outside copy and document processing entity or person retained by any party in connection with the litigation; and (5) attorneys involved in a pending, filed, and served Reglan®/metoclopramide case against the producing party who have a) produced affirmative product identification against the producing party, b) read the Amended Agreed Protective Order, and c) provided an affidavit attesting to the fact that they have read and agreed to be bound by the terms of this Amended Agreed Protective Order. The parties agree that the documents designated as confidential may be revealed to additional persons, including parties, by agreement, which shall not be unreasonably withheld. In-house counsel is specifically excluded from this group due to the competitive advantage that may be gained by obtaining another defendants' confidential and/or trade secret information.

B. With the exception of counsel as defined in Paragraph 2.A(5), such person who reviews or inspects confidential documents or information subject to this Amended Agreed Protective Order shall be brought within the personal jurisdiction of this court, including its contempt power, by signing a copy of the

attached affidavit signifying agreement to the provisions of this Amended Agreed Protective Order and consenting to the jurisdiction of this Court over his or her person for any proceedings involving alleged improper disclosure of said protected documents or information. Each person's signature shall be notarized by an officer authorized to administer oaths.

- C. With the exception of counsel as defined in Paragraph 2.A(5), no person entitled to access to protected documents or information under this Amended Agreed Protective Order shall be provided with the protected documents or information unless such individual has first read the Amended Agreed Protective Order of this court and completed and signed the affidavit provided. No person entitled to access protected documents or information shall disclose or discuss the existence or contents of any such materials with any other individual, except those individuals who are also permitted to view, inspect or examine the materials protected herein. The information protected by this Amended Agreed Protective Order shall be used for the sole purpose of the preparation for this case, and shall not be used for any other purpose or for any other legal action except as provided by this Amended Agreed Protective Order.
- D. Each party's counsel shall maintain a list of the names of all persons who inspect or review confidential documents obtained from another party prior to trial of this matter or who receive any copies of such confidential documents. Each party will produce a copy of the executed Exhibit A for each of its testifying

experts to whom confidential documents were provided upon request, but no earlier than the time of the party's expert designation. For purely consulting experts, the party retaining the expert shall furnish copies of the executed Exhibit A for each consulting expert where good cause is shown. This provision in no way alters or expands the terms of Paragraph 2.A of this Amended Agreed Protective Order identifying the persons to whom confidential material may be revealed.

3. RETURN OF DOCUMENTS AND INFORMATION. Copies of documents and information produced by a defendant may remain in the possession of the undersigned plaintiff's attorneys and other counsel as defined in Paragraph 2.A(5) in which the producing party is a defendant. The documents and information produced by a defendant may not be used for any other purpose nor disclosed to any other person except as provided by this Order. Within thirty (30) days after the conclusion of the last of the Reglan®/metoclopramide cases filed by the undersigned plaintiffs' attorneys against the producing defendant, the undersigned plaintiffs' attorneys shall produce the list of persons, other than purely consulting experts, who inspected or reviewed confidential documents and shall either (1) return all the documents and information to the producing defendant at a location selected by the producing defendant and at the undersigned plaintiffs' attorneys' expense, or (2) produce an affidavit executed by the undersigned plaintiffs' attorneys indicating that all of the documents from the producing defendant have been destroyed or will be destroyed within forty-five (45) days from the date the affidavit is executed. This Amended Agreed Protective Order remains in full force and effect and governs the use of the documents and information.

- 4. <u>APPLICATION TO THE COURT</u>. Nothing herein shall be construed to preclude or limit any party from opposing any discovery on any ground which would otherwise be available. Nothing in this Amended Agreed Protective Order shall be deemed to preclude any party from seeking or obtaining, on the appropriate showing, additional protection with respect to the confidentiality of documents or information. Nothing in this Amended Agreed Protective Order shall preclude any party from seeking or obtaining, on the appropriate showing, an order lifting the protection granted in this Amended Agreed Protective Order with respect to the confidentiality of documents or information.
- 5. <u>ADMISSION INTO EVIDENCE</u>. The terms of this Amended Agreed Protective Order shall not be construed as any limitation upon the right of any party to offer into evidence any documents, response, or information designated as confidential.
- 6. <u>VIOLATION OF AMENDED AGREED PROTECTIVE ORDER</u>. A violation by any person of any provision of this Amended Agreed Protective Order may be punishable as determined by the court. Further, the parties may

pursue any and all civil remedies available for breach of the terms of this Amended Agreed Protective Order.

7. <u>JURISDICTION OF COURT</u>. This court retains jurisdiction over the parties, counsel for the parties, and all persons, firms, corporations, or organizations, whomsoever, to whom this Amended Agreed Protective Order applies, for purposes of enforcement of this Amended Agreed Protective Order following the conclusion of this action.

8. CHALLENGE TO CONFIDENTIALITY DESIGNATION.

A. If a party elects to challenge any designation of confidentiality of any documents or information pursuant to this Amended Agreed Protective Order, that party shall provide the designating party thirty (30) days advance written notice and afford the producing party opportunity to voluntarily remove such designation. The producing party shall, within thirty (30) days of the receipt of such notice, either voluntarily remove the designation or file a written motion with the court for an order preventing or limiting disclosure. Each such motion shall be accompanied by one copy of each document, response, or portion or transcript challenged, following the provision set forth above in Paragraph 1.C of this Amended Agreed protective Order, and the confidentiality of such information shall remain protected until the Court shall order otherwise. In the event the producing party files a motion seeking protection of challenged

documents or information, the party opposing the motion shall respond to the motion and the producing party shall have the opportunity to reply.

The interested parties shall attempt to resolve any such challenge by agreement prior to the time for filing of a motion as herein provided. If the challenge is not resolved by agreement, or by voluntary removal, and if no motion is filed within thirty (30) days of the receipt of written notice of challenge, then the confidential designation shall be removed and shall not thereafter apply to such documents or information.

- B. All documents, testimony, or other materials designated by the producing party as confidential shall retain their confidential status during the pendency of any proceeding challenging confidentiality until such time as the parties' contentions are fully and finally adjudicated, including such appeals as may be sought.
- C. Neither this Amended Agreed Protective Order nor the designation of any item as confidential materials shall be construed as an admission that such material or any testimony in respect to such material in a deposition or otherwise would be admissible in evidence in this litigation or in any other proceeding. In addition, this Amended Agreed Protective Order does not, of itself, require the production of any information or document.
- 9. THIRD PARTY REQUEST FOR CONFIDENTIAL DISCOVERY

 MATERIAL. If confidential documents or information in the possession of a

receiving party is subpoenaed or requested by any court, administrative or legislative body, or any other person or organization purporting to have authority to subpoena or request such data or information, the party to whom the subpoena or request is directed shall not, to the extent permitted by applicable law, provided or otherwise disclose such documents or information without waiting ten (10) business days after first notifying counsel for the producing party in writing of: (1) the information and documentation which is requested for production in the subpoena or request; (2) the date on which compliance with the subpoena or request is sought; (3) the location at which compliance with the subpoena or request is sought; (4) the identity of the party serving the subpoena or making the request; and (5) the case name, jurisdiction, and index, document, complaint, charge, civil action, or other identification number or designation identifying the litigation, administrative proceeding, or other proceeding in which the subpoena or request has been issued.

10. <u>INADVERTENT OR UNINTENTIONAL DISCLOSURE</u>. Any inadvertent or unintentional disclosure of confidential and proprietary material will not be construed as a waiver, in whole or in part, of (1) the producing party's claims of confidentiality either as to the specific information inadvertently or unintentionally disclosed or as to any other confidential material disclosed prior to or after that date, or (2) the producing party's right to designate said material as confidential material pursuant to this Amended Agreed Protective Order. This

Amended Agreed Protective Order does not in any way deprive a party of its right

to contest the producing party's claims to protection for confidential proprietary,

and trade secret information. Nor does this Amended Agreed Protective Order in

any way deprive the producing party of its right to claim that such information

should be protected from disclosure. Production of documents or information

pursuant to this Amended Agreed Protective Order shall not be construed as a

waiver of any sort by the parties.

11. Nothing herein shall be construed or applied to effect the rights of

any party to discovery under the Federal Rules of Civil Procedure, or to assert

any objection, or to prohibit any party from seeking such further provisions or

relief as it deems necessary or desirable regarding this Amended Agreed

Protective Order, including but not limited to an order that discovery not be had.

SIGNED AND ORDERED ENTERED ON THIS 21st DAY OF

SEPTEMBER, 2010.

VICKI MILES-LaGRANGE

CHIEF UNITED STATES DISTRICT JUDGE

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APPROVED:

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